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Indian Standard

POSITIVE LIST OF CONSTITUENTS OF MODIFIED POLY (PHENYLENE OXIDE) (PPO) IN CONTACT WITH FOODSTUFFS, PHARMACEUTICALS AND DRINKING WATER

ICS 67.250; 83.080.20

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BUREAU OF INDIAN STANDARDS
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
NEW DELHI 110002

October 2001 **Price Group 3**

Plastics Sectional Committee, PCD 12

FOREWORD

This Indian Standard was adopted by the Bureau of Indian Standards, after the draft finalized by Plastics Sectional Committee had been approved by the Petroleum Coal and Related Products Division Council.

Plastics are being used on a large scale for packaging of foodstuffs, pharmaceuticals and drinking water. Where direct contact occurs between the packed commodity and the plastics, the high-molecular mass polymer itself does not pose a toxic hazard being inert and essentially insoluble in food. There is, however, a likelihood that some transfer of polymer additives, adventitious impurities such as monomers, residual catalysts remnants and residual polymerization solvents and of low molecular mass polymer fractions will occur from the plastics into the packaged material with consequent toxic hazard to the consumer. The occurrence of acute toxicity due to plastics material in contact with food is most unlikely, since only trace quantities of potentially toxic material are likely to migrate. However, the accumulation of these potentially toxic materials with time may lead to hazards which may be serious.

Polyphenylene oxide (PPO) or poly[1,4-(2,6-dimethyl phenyl)] ether was discovered by John Hay in 1956 and was developed commercially by General Electric company under the trade name Noryl resins 1965-66.The chemical formulation is based on the oxidative coupling of substituted phenols and the elimination of a molecule of water. PPO resins are usually alloyed with polystyrene materials. It acts as a base for a large family of resins with typical heat distortion temperature ranging from 82°C to more than 150°C. The chemical resistance characteristics of PPO are fairly consistent. These resins are noted for their resistance to hydrolysis in acids, bases, salts and hot water ,but can be attacked by certain hydrocarbons, esters, ketones, amines and halogenated compounds. PPO resins offer the designer a combination of attractive properties including heat resistance, good impact strength, strong tensile and flexural properties at elevated temperatures and a wide processing range. They also feature low specific gravity and low moisture absorption rates. High energy radiation such as gamma or X-rays cause little loss of properties of the UV stabilized grades, even at high doses. Moulded articles can be sterilized by autoclave, gas or irradiation without any harm to the materials.

PPO resins can be processed in a number of ways, but the bulk of applications are in injection moulding. PPO can also be extruded and thermoformed and various processes such as blow moulding, compression moulding, cold forming and rotational moulding have been used with varying degrees of success. Modified PPO resins find wide usage in food contact and health care applications. Some of the most important and known applications of modified PPO resins in this area are pump impellers and diffusers, filter press components, sterlizable trays, stopcocks, etc.

Use of modified PPO resins is guided by EEC directives 90/128/EEC in Europe. In USA, it is regulated by FDA regulations 21 CFR 177.2460. For potable water applications several grades of modified PPO resins are registered under BVGW and Hygiene Institute, Gelsenkirchen (Germany). Institute d' Analysis et d' Essais du Centre-Quest (France) and WRC (UK).

This standard is intended to be used with a series of Indian Standards on plastics for food contact applications which are given in Annex A. It is emphasized that these standards need to be used in combination to provide a system of control to the manufacturers of plastics as well as the fabricators of thermoplastics packaging materials to derive maximum benefit besides, it may also serve as basis for official agencies to frame suitable legislation to ensure effective safeguards for the safety and health of consumers where thermoplastics for food contact and related applications are concerned.

The composition of the Committee responsible for formulation of this standard is given in Annex B.

Indian Standard

POSITIVE LIST OF CONSTITUENTS OF MODIFIED POLY(PHENYLENE OXIDE)(PPO) IN CONTACT WITH FOODSTUFFS, PHARMACEUTICALS AND DRINKING WATER

1 SCOPE

1.1 This standard covers positive list of constituents of modified (polyphenylene oxide) (PPO), namely, the polymer raw materials, manufacturing residues and necessary additives which may be regarded as safe for use when properly processed in contact with foodstuffs, pharmaceuticals and drinking water and when present only in the prescribed limits of concentration.

1.2 It does not purport to establish the suitability of the ingredients singly in a particular foodstuffs from other than toxicological considerations.

2 REFERENCE

The following standard contain provisions, which, through reference in this text, constitute provisions of the standard. At the time of publication, the edition indicated was valid. All standards are subject to revision, and parties to agreement based on the standard are encouraged to investigate the possibility of applying the most recent edition of the standard indicated below:

IS No.	*Title*
9833 : 1981	List of pigments and colourants for use in plastics in contact with foodstuffs, pharmaceuticals and drinking water

3 TERMINOLOGY

3.1 Modified (Polyphenylene Oxide) (PPO)

A polymeric alloy based on PPO resin produced by oxidative coupling reaction of 2,6-dimethyl phenol and other thermoplastics materials like high impact polystyrene (HIPS), acrylonitrile-butadiene-styrene (ABS), polycarbonate (PC), polyamides (PA), etc.

4 REQUIREMENTS

4.1 Basic Resins

4.1.1 *Individual Modified PPO*

4.1.1.1 As defined in **3.1** in any mixing proportion.

4.1.1.2 Modified PPO materials shall comply with the requirements such as raw material used, limit of manufacturing residues and additives and their acceptable level of addition as described in subsequent clauses.

4.2 Raw Materials

In manufacturing PPO to be used in modified PPO materials for safe use in contact with foodstuffs, pharmaceuticals and drinking water following reactive raw materials can be used:

a) 2,6-dimethyl phenol; and
b) Oxygen.

4.3 Manufacturing Additives/Residues

Following manufacturing additives can be used in the manufacture of PPO resin within specified limits.

4.3.1 *Initiators*

a) 2,2'azobis (*iso*-butyronitrile), *Max* 0.5 percent;
b) Tert, butylperoxy diethylacetate, *Max* 0.5 percent;
c) Copper 1 bromide, *Max* 1.0 percent;
d) Diacyl (C_6- C_{14}) peroxides, *Max* 0.5 percent;
e) Dibenzoyl peroxide, *Max* 0.5 percent;
f) Dibutral amine, *Max* 1.0 percent;
g) Dibutylethylenediamine, *Max* 0.2 percent; and
h) Dimethylbutylamine, *Max* 0.2 percent.

4.3.2 *Emulsifier Residues*

a) Alkyl (C_8- C_{18})benzene sulphonates, sodium salts, *Max* 1.0 percent;
b) Alkyl (C_8- C_{18}) sulphates, sodium salts, *Max* 1.0 percent;
c) Alkyl (C_8- C_{18}) sulphonates, sodium salts, *Max* 1.0 percent; and
d) Polyethylene oxide (C_8- C_{14}) esterified with lauric, oleic, ricinolaic and/or stearic acid, *Max* 1.0 percent.

4.3.3 *Solvent Residues*

a) Methanol, *Max* 0.002 percent; and
b) Toluene, *Max* 0.2 percent.

4.4 Following additives can be incorporated into basic PPO resin to manufacture modified PPO materials provided their level of addition is within the limit, where specified.

4.4.1 *Polymers*

Complying with the relevant Indian standards for its safe use in contact with food stuffs, pharmaceuticals and drinking water (*see* Annex A).

4.4.2 *Lubricants and Release Agents*

a) Fatty acids, linear, saturated and unsaturated with an even number of carbon atoms (C_8–C_{22}),with *Max* 2 percent of unsaponified matter, *Max* 2 percent;

b) Fatty acids as described above esterified with alcohols, monohydric, primary linear, saturated, C_{14}– C_{16}, as well as oleic alcohol and pentaerythritol, *Max* 2 percent;

c) Fatty acids as described above, as salts with aluminium, calcium, potassium, magnesium, sodium and zinc, *Max* 2 percent;

d) Liquid paraffin (refined mineral oil), *Max* 3 percent;

e) Microcrystalline paraffin, *Max* 3 percent; and

f) Polydimethyl siloxane, *Max* 2 percent.

4.4.3 *Stabilizers and Antioxidants*

a) Bis (2,4-di-tert butylphenyl) pentaerytritol-diphosphites, *Max* 0.25 percent;

b) 2,2-methylenebis (4-methyl-6-tert butyl phenol),*Max* 0.3 percent;

c) Octadecyl-3-(3,5-di-tertbutyl-4-hydroxy-phenyl) propionate, *Max* 0.3 percent;

d) Phosphates of calcium and sodium, *Max* 1 percent;

e) Poly{6-(1,1,3,3-tetramethyl butyl)amino}-1,3,5-triazine-2,4-diyl]–[(2,2,6,6-tetramethyl-4-piperidyl)-imino]-hexamethylene [(2,2,6,6-tetramethyl-4-piperidyl)imino], *Max* 3 percent;

f) Tris (2,4-di-tert, butylphenyl) phosphite, *Max* 0.3 percent;

g) Zinc oxide, *Max* 0.3 percent; and

h) Zinc sulphide, *Max* 0.3 percent.

3.4.4 *Antistatic Agent*

Polypropylene oxide, molecular weight > 400, *Max* 1.0 percent.

3.4.5 *Pigments and Colourants*

The pigments and colourants used shall comply with list and limits prescribed in IS 9833.

3.4.6 *Other Additives*

a) Acetic anhydride;

b) Carbonates and bicarbonates of calcium, potassium and sodium, *Max* 2.0 percent;

c) Citric acid, calcium, potassium and sodium salts, *Max* 2.0 percent;

d) Copper (II) iodide, *Max* 0.1 percent;

e) Magnesium oxide, *Max* 0.3 percent;

f) Phosphates of calcium, *Max* 1.0 percent;

g) Potassium iodide, *Max* 0.5 percent;

h) Salicylic acid; and

j) Silicates of aluminium, calcium, potassium, magnesium and sodium including diatomaceous earth, glass fibres, kaolin, mica and talc, *Max* 3.0 percent.

ANNEX A

(*Foreword*)

LIST OF INDIAN STANDARDS ON PLASTICS SUITABLE FOR USE IN CONTACT WITH FOODSTUFFS, PHARMACEUTICALS AND DRINKING WATER

IS No.	*Title*
9833 : 1981	List of pigments and colourants for use in plastics in contact with foodstuffs, pharmaceuticals and drinking water
9845:1998	Determination of overall migration of constituents of plastics materials and articles intended to come in contact with foodstuffs — Method of analysis (*second revision*)
10141 : 2001	Positive list of constituents of polyethylene in contact with foodstuffs, pharmaceuticals and drinking water (*first revision*)
10142 : 1999	Polystyrene (crystal and high impact) for its safe use in contact with foodstuffs, pharmaceuticals and drinking water (*first revision*)
10146 : 1982	Polyethylene for its safe use in

IS No.	*Title*
	contact with foodstuffs, pharmaceuticals and drinking water
10148 : 1982	Positive list of constituents of polyvinyl chloride and its copolymers for safe use in contact with foodstuffs, pharmaceuticals and drinking water
10149 : 1982	Positive list of constituents of polystyrene (crystal and high impact) in contact with foodstuffs, pharmaceuticals and drinking water
10151 : 1982	Polyvinyl chloride (PVC) and its copolymers for its safe use in contact with foodstuffs, pharmaceuticals and drinking water
10171 : 1999	Guide on suitability of plastics for food packaging (*second revision*)
10909 : 1984	Positive list of constituents polypropylene and its copolymers for its safe use in contact with foodstuffs, pharmaceuticals and drinking water (*first revision*)
10910 : 2001	Polypropylene and its copolymers for its safe use in contact with foodstuffs, pharmaceuticals and drinking water
11434 : 1985	Ionomers resins for its safe use in contact with foodstuffs, pharmaceuticals and drinking water
11435 : 1985	Positive list of constituents of ionomer resins for its safe use in contact with foodstuffs, pharmaceuticals and drinking water
11704 : 1986	Ethylene/acrylic acid (EAA) copolymers for its safe use in contact with foodstuffs, pharmaceuticals and drinking water
11705 : 1986	Positive list of constituents of Ethylene/acrylic acid (EAA) copolymers for their safe use in contact with foodstuffs, pharmaceuticals and drinking water
12229 : 1987	Positive list of constituents of polyalkylene terephthalates (PET & PBT) for their safe use in contact with foodstuffs, pharmaceuticals and drinking water
12247 : 1988	Nylon-6 polymer for its safe use in contact with foodstuffs, pharmaceuticals and drinking water
12248 : 1988	Positive list of constituents of Nylon-6 polymer for its safe use in contact with foodstuffs, pharmaceuticals and drinking water
12252 : 1987	Polyalkylene terephthlates (PET& PBT) for their safe use in contact with foodstuffs, pharmaceuticals and drinking water
13449 : 1992	Positive list of constituents of ethylene vinyl acetate (EVA) copolymers in contact with foodstuffs, pharmaceuticals and drinking water
13576 : 1992	Ethylene methacrylic and (EMAA) copolymers and terpolymers for their safe use in contact with foodstuffs, pharmaceuticals and drinking water
13577 : 1992	Positive list of constituents of ethylene methacrylic (EMAA) copolymers and terpolymers in contact with foodstuffs, pharmaceuticals and drinking water
13601 : 1993	Ethylene vinyl acetate (EVA) co-polymers for its safe use in contact with foodstuffs, pharmaceuticals and drinking water
14971 : 2001	Polycarbonate resins for its safe use in contact with foodstuffs, pharmaceuticals and drinking water
14972 : 2001	Positive list of constituents of polycarbonate resins in contact with foodstuffs, pharmaceuticals and drinking water
14997 : 2001	Modified poly (phenylene oxide) (PPO) resins for its safe use in contact with foodstuffs, pharmaceuticals and drinking water
14998 : 2001	Positive list of constituents of melamine-formaldehyde resins in contact with foodstuffs, pharmaceuticals and drinking water
14999 : 2001	Melamine-formaldehyde resins for its safe use in contact with foodstuffs, pharmaceuticals and drinking water

ANNEX B

(*Foreword*)

COMMITTEE COMPOSITION

Plastics Sectional Committee, PCD 12

Organization	*Representative(s)*
Internet Exchange Next.com Limited, Mumbai	Shri Sarup Chowdhary (*Chairman*)
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